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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,852	08/14/2001	William H. Hildebrand	6680.025	9815

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EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	9

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/929,852	HILDEBRAND, WILLIAM H.	
	Examin r	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1,2 and 5-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-2, in Paper No. 7 filed 3-26-03, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
It is noted that Applicant cancelled non-elected claims 3 and 4 in Applicant's Amendment filed 3-26-03. In said amendment, Applicant newly added claims 5-8.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

3. The substitute specification filed 3-26-03, (Paper No. 8) has not been entered because it does not conform to 37 CFR 1.125(b)because: the statement as to a lack of new matter under 37 CFR 1.125(b) is missing.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-2 and 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. A) Claims 1-2 and 5-8 are indefinite in their recitation of the phrase "isolating MHC allele mRNA" because it is not clear what is meant and the specification does not define MHC allele mRNA.
7. B) Claim 8 is indefinite in its recitation of the phrase "wherein , in the step of isolating MHC allele mRNA from a source, the source is selected from the group consisting of a mammalian DNA specimen" because it is not clear how mRNA can be isolated from DNA.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prillman et al (Immunogenetics, Vol. 45, pages 379-385, 1997) in view of Maniatis et al (Molecular Cloning: A Laboratory Manual, second Edition, Cold Spring Harbor laboratory, pages 129 and 191-192, 1982).

Prillman et al. teaches a method for the large scale production of an allele of the individual human Class I molecule HLA-B*1501, wherein said molecule is soluble, comprising PCR amplification of a single strand of full length DNA clone of HLA-B*1501 with primers one of which introduced a stop codon and served to truncate the expressed form of the molecule through removal of the transmembrane and cytoplasmic regions from the coding region, followed by cloning the PCR product into an expression vector (pBJ-1neo) to create a construct, followed by transfection of the construct into the immortalized class I negative cell line 721.221, followed by large scale growth of the transfected cells by inoculating the cells into a hollow fiber bioreactor system, growing said cells, and the harvesting of soluble MHC class I molecules (see entire article, especially page 380 and the Abstract). Prillman also teaches using such a production scheme for soluble class I molecules followed by mass spectroscopy sequencing of peptides eluted from said soluble HLA molecules, so that peptide binding signatures could be assigned to individual class I molecules and thus clarify the basis of peptide based vaccines. (See entire article, especially the last paragraph on page 384).

Prillman does not teach PCR amplification from a source of RNA.

Maniatis et al (1982) teach the isolation of mRNA from mammalian cells and the use of reverse transcriptase to transcribe mRNA into cDNA a protocol that is used chiefly to transcribe mRNA into double stranded DNA that can be inserted into vectors (see especially pages 129 and 191-192)

Therefore, it would have been obvious to one of skill in the art who wanted to produce soluble HLA molecules as part of a method of assigning peptide binding signatures to individual HLA molecules as a means of assessing the efficacy of peptide based vaccines, as taught by Prillman et al., to have used the methods taught by Prillman et al. for the production of a soluble HLA Class I molecule, and to have adapted the method of Prillman et al. to encompass an MHC

Class I molecule other than the HLA-B*1501 exemplified by Prillman et al, since Prillman et al. teaches that their technique can be applied to assigning the peptide signatures of other HLA molecules in addition to HLA-B*1501. Since the starting material of Prillman et al. (a single strand of full length DNA clone of HLA-B*1501) would not have been appropriate for another MHC molecule, one of skill would have been motivated to have isolated mRNA and reversed transcribed it using primers specific for the individual MHC Class I molecule under study as taught by Maniatis, in order to produce a cDNA substrate for cloning the soluble class I MHC molecule according to the method of Prillman et al, since Prillman et al. teaches that her technique can be applied to assigning the peptide signatures of other HLA molecules in addition to HLA-B*1501, and since Maniatis teaches the isolation of mRNA from mammalian cells and the use of reverse transcriptase to transcribe mRNA into cDNA a protocol which is used chiefly to transcribe mRNA into double stranded DNA which can be inserted into vectors. With regard to the limitations of claim 2 , the recited limitations are expected conditions and steps used in growing cells in a hollow fiber bioreactor.

From the referenced teachings it is apparent that one of ordinary skill in the art at the time the invention would have had a reasonable expectation of success in producing the claimed invention because the limitations of the claimed methods were well known at the time the invention was made for the purpose of producing large amounts of soluble class I HLA.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner.
Group 1640
June 9, 2003

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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